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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/521,907 | 03/09/2000 | Stale Petter Lyngstadaas | 49121 | 2801 |
| 21874 | 7590 | 12/14/2004 | EXAMINER | |
| EDWARDS & ANGELL, LLP | | | SAUNDERS, DAVID A | |
| P.O. BOX 55874 | | | ART UNIT | |
| BOSTON, MA 02205 | | | PAPER NUMBER | |

1644

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

521,907

Applicant(s)

LYNGSTAD AAS et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/28/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 28-35, 41-55 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 28-35, 41-55 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The amendment of 9/28/04 has been entered. Claims 28-35 and 41-55 are pending and under examination. The amendment has entered no new matter. The following correction pertains to the previous office actions, mailed 6/21/04: at page 3, line 1, "claim 1" should have read as --claim 28--.

The amendment of 9/28/04 has overcome all bases of rejection under 35 USC 112, first and second paragraph, except as stated infra for the amended claims.

Claims 28-35 and 41-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28, step c), "the pre-treated..." lacks antecedent basis because no previous step has recited anything about "pre-treating". Applicant's amendment has substituted "the pretreated" in lieu of "said-pretreated"; however, this fails to avoid the failure to provide antecedent basis.

Furthermore, one cannot even infer what agent/composition might be employed in a "pre-treating" step. Note that dependent claim requires the enamel substance to be applied to the recipient bed or lesion before application of the graft of step c). If one assumes that claim 30 further limits base claim 28, then one would conclude that claim 30 must more broadly also encompass an embodiment in which step b) follows step c); in such case "the pre-treating" recited in step c) must refer to a "treating" with some agent/composition other than the "active enamel substance" of step b). One has no idea what this other agent is.

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If on the other hand, applicant considers that the "pre-treating" of step c) refers to what was applied to the graft bed or lesion in step b), then claim 30 encompasses everything encompassed by base claim 28; in such case claim 30 must be cancelled.

Claims 29-31 are confusing by reciting, "is applied" since no "applying" step has been recited in base claim 28. Consistent terminology is required in claim 28 and all dependent claims.

As amended, claim 28 is confusing in step b) by reciting "prophylactically effective amount." One cannot infer what reaction/process/condition is supposed to be prevented. One thus does not know what is to be effected by "effective amount" of the enamel substance. Note ^{at} previously the claim preamble had recited "promoting the take of a graft", by which one could infer what process the enamel substance is intended to promote; presently the preamble is silent in this respect.

The amendment has overcome the previously stated rejections under 35 USC 112, first paragraph.

The amendment has necessitated the following objection to claim 35:

Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 35 "epidermal cells" is broader in scope than the "cultured epidermal cells" of base claim 28; thus claim 35 fails to further limit claim 28.

To place in condition for allowance applicant must

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- 1) provide for proper antecedent basis of "pre-treated" in step c) of claim 28.
- 2) provide a context by which a "prophylactically effective amount" in step b) of claim 28 can be understood.
- 3) provide for steps b) and c) of claim 28 to be conducted in order
- 4) cancel claim 30.
- 5) provide consistent language in claims 29-31, as the^y refer to step b) of base claim 28.
- 6) cancel claim 35 or amend, in a manner supported, so as to further limit claim 28.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

December 10, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644